REMARKS

The interview conducted on October 2, 2003 consisted of a discussion of various proposed claim amendments and reasons for the patentability of the claims over the cited references. Some of the proposed claim amendments were identified as mere clarifications while others were identified as helping to differentiate the claimed invention over the cited references.

Due to time constraints, the Examiner requested that the interview be terminated before it was completed and that the Applicants submit an Amendment and Response detailing the reasons for patentability. The Examiner agreed to review the filed Amendment and Response and contact the Applicants to further the telephonic interview if any questions arose. Accordingly, all of the discussed claim amendments were entered in the Amendment and Response filed October 6, 2003.

More particularly, a proposed clarifying amendment to claims 21 and 33 was discussed. These amendments were identified by the Examiner as acceptable and were entered in the Amendment and Response filed October 6, 2003. Additional comments regarding these amendments can be found on pages 15-16 of that Amendment and Response. As was noted therein, these amendments do not affect the patentability of the claims or narrow the scope of the claims.

The attorney for the Applicant then discussed with the Examiner the primary differences between United States Patent No. 5,470,581 to Grillo ("*Grillo*") and the claimed invention. The discussed differences can be summarized briefly by reference to the proposed (and now entered) limitations of claim 1: "wherein, upon **mixing** with a bioactive substance . . . the cellulose and the maltodextrin slow the disintegration of the orally administered specimen to provide a sustained release of the bioactive substance." It was noted that *Grillo*, in contrast, discloses a method of **coating** pharmaceutical tablets and the like. *Grillo's* coating cannot be mixed with a medicament

and is therefore not sustained release (delayed release perhaps, but not sustained release). A further discussion of this and other differences is presented in the previously filed Amendment and Response.

Next, the attorney for the Applicant and the Examiner discussed proposed amendments that were intended to distinguish the relevant claims from *Grillo*. The proposed amendments were identified to the Examiner as responsive to the stated "Response to Arguments" section in the previous Office Action. In particular, the attorney for the Applicant noted the Examiner's language from the Response to Arguments Section of the Office Action: "the limitation, 'distributed throughout the orally administered specimen' permits the film forming around the dosage form taught by *Grillo*" and "it is noted that the language upon which the Applicant relies (i.e. slows the disintegration of the table; and protect a stomach wall from direct contact with a medicine or supplement) are not recited in the claims." Office Action, p. 6. The discussed proposed claim amendments to claim 1, 21, and 33 focused on this language to attempt to craft claims that the Examiner would allow as patentable over *Grillo*. Because of the time restraints, the Examiner requested that a formal submission be made so that the Examiner could review the Applicants arguments in greater detail before agreeing that the amended claims are patentable over *Grllo*. Accordingly, the Applicants argument was reduced to text and can be found in the Amendment and Response filed October 6, 2003.

In turn, the Examiner suggested the addition of claims to recite specific ranges for the release profile of the inventive sustained release compositions. The Examiner suggested that such claims would distinguish the Applicants' sustained release compositions from *Grillo's* delayed release capsules. These claims were not entered by the Applicant because it was felt, upon review, that such

claims were not necessary to distinguish the invention over the prior art. Applicants believe that the specific recitation of a time frame for sustained release is not necessary to distinguish between the already distinct actions inherent in the term sustained release and *Grillo's* delayed release.

Finally, one apparent area of confusion that was also discussed was the meaning of "the maltodextrin and the cellulose provide the sustained release of the bioactive substance for a time period, and this time period is at least one hour" in claim 21. The attorney for the Applicant noted that the term "sustained release" refers to a slow disintegration of the tablet, not a delayed disintegration. For reference, paragraph 10 of the specification states:

> **[010]** To achieve the foregoing objects, and in accordance with the invention as embodied and broadly described herein, compositions according to the present invention comprise combinations of maltodextrin and cellulose. **The cellulose is preferably used in the form of powdered cellulose, and its combination with maltodextrin provides gelling effects and it slows the disintegration of the tablet**, thus contributing to the sustained release of the medicine or supplement in the tablet. In addition, the gelling effects prevent the direct contact with the stomach wall of a substantial amount of the possibly irritant medicine or supplement.

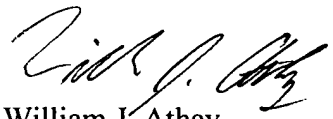
(emphasis added). Other examples of usage of the term "slow release" that illuminate its meaning include: "[t]he cellulose is preferably used in the form of powdered cellulose, and its combination with maltodextrin provides gelling effects and it **slows the disintegration of the tablet, thus contributing to the sustained release** of the medicine or supplement in the tablet (para. 10); and "[t]he present invention is directed to sustained release compositions that **slow the disintegration of the delivery specimen**" (para. 16) (emphasis added). *See also* para. 40, ("[T]he sustained release composition of the present invention effectively provides a release medium and release mechanism such that the active substance is gradually and continuously incorporated into the receiving environment.").

CONCLUSION

In view of the foregoing, Applicants respectfully request favorable reconsideration and allowance of the present claims. In the event the Examiner finds any remaining impediment to the prompt allowance of this application that could be clarified by a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney.

Dated this 17th day of November, 2003.

Respectfully submitted,



William J. Athay
Attorney for Applicants
Registration No. 44,515
Customer No. 022913

W:\10265\96.1\WJA0000000445V001.doc